

Congress of the United States
Washington, DC 20515

June 9, 2015

Mr. Gene Dodaro
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, DC 20548

Dear Mr. Dodaro:

Multiplex Point-of-Care Testing (POCT)¹ technology – one of the fastest growing technologies worldwide – enables rapid diagnostic tests to be performed while the patient is at a point of care facility, such as a doctor's office or clinic. Also known as Point-of-Care Diagnostics, POCT results can be obtained rapidly, rather than waiting hours or even days for outside laboratory results to arrive. This allows for faster interpretation of test results by medical personnel and subsequent treatment of the patient. POCT technology is available in multiple platforms (for example, PCR assays for nucleic acids, or immunoassays for protein targets). Multiplexing this technology enables multiple tests (potentially up to hundreds of tests) to be run in a single reaction, representing a potential improvement over uniplex testing, which runs each test in its own reaction. Multiplexing thus generates rapid results with resulting gains in testing efficiency, such as conserving expensive chemicals. The implications for our public health systems are substantial, including specific benefits related to homeland security and biothreats.

In recent years, there has been significant investment from both the private and public sectors in the development of diagnostic technologies. Multiplex POCT systems are of interest to several federal government agencies, including the Department of Health and Human Services (HHS), Department of Homeland Security (DHS), and the Department of Defense (DOD), with some agencies providing investment funding to develop or acquire these capabilities. These systems could significantly expedite diagnoses and reduce healthcare costs.

However, a recent report from the DHS Office of Inspector General raised concerns about the DHS's contract management in this area. For example, DHS supported a project developed by NVS Technologies, Inc., for a multiplex POTC prototype, indicating it would

¹ Also referred to as Point-of-Care Diagnostics.

“provide a robust, specific, and sensitive suite of detection assays that can be used by Federal Laboratories and the private sector. . .”² In October 2011, DHS testified before the Senate Homeland Security Committee, mentioning this technology as an example of federal strategic investments that “have yielded valuable insights.”³ According to DHS, this technology had the additional capability of detecting select agents such as dangerous biothreat agents that could be used by terrorists, and providing earlier detection than is possible with manual surveillance systems (including the currently deployed BioWatch system), which is crucial for mitigating consequences and saving lives in the event of an attack.

In November 2013, a single DHS management official directed the termination of the NVS Technologies contract against DHS subject matter experts’ advice. The Office of DHS Inspector General, in an audit report, found that DHS may have wasted \$23 million in incurred cost by the decision to cancel continued funding of the project.⁴ The support and then eventual cancellation of this project is just one example that raises questions about DHS investments and progress in developing POTC technology.

To ensure effective oversight and policy direction, Congress must understand the status of these technologies, including the extent to which their performance (including sensitivity, specificity, and limits of detection) is known. Therefore, we are asking GAO’s Center for Science, Technology, and Engineering to conduct a technology assessment of multiplex POCT to address the following questions:

1. What is known about the performance characteristics of commercially available multiplex POCT, including the NVS technology?
2. What technical issues are associated with multiplexing assays used in such technology?
3. What are the known benefits, costs, and implementation challenges of this technology?

If you have any questions regarding this request, please contact Alan Slobodin of the House Energy and Commerce Committee at 202-225-2927 and Gabe Sudduth of the Senate Homeland Security and Governmental Affairs Committee at 202-224-0828.

Sincerely,



Fred Upton
Chairman
House Energy and Commerce Committee



Ron Johnson
Chairman
Senate Homeland Security and Governmental
Affairs Committee

² U.S. Department of Homeland Security Annual Performance Report, Fiscal Years 2012-2014, 20.

³ Written testimony of the Honorable Tara O’Toole, M.D., M.P.H., DHS Under Secretary for Science and Technology, before the Senate Committee on Homeland Security and Governmental Affairs, October 18, 2011.

⁴ Office of Inspector General, Department of Homeland Security, “Science and Technology Directorate Needs to Improve Its Contract Management Procedures,” OIG-15-38 (February 27, 2015).